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L4: Entry 3 of 4

File: EPAB

Feb 27, 2003

PUB-NO: WO003015822A1

DOCUMENT-IDENTIFIER: WO 3015822 A1

TITLE: 5-CNAC AS ORAL DELIVERY AGENT FOR PARATHYROID HORMONE FRAGMENTS

PUBN-DATE: February 27, 2003

INVENTOR-INFORMATION:

COUNTRY NAME CH AZRIA, MOISE US BATEMAN, SIMON DAVID ASSIGNEE-INFORMATION: COUNTRY NAME CH NOVARTIS AG AT NOVARTIS PHARMA GMBH CH AZRIA MOISE US BATEMAN SIMON DAVID APPL-NO: EP00209181 APPL-DATE: August 16, 2002 PRIORITY-DATA: US31304801P (August 17/, 2001)

INT-CL (IPC): A61 K 47/18; A61 K 38/29; A61 P 19/08; A61 P 19/10

EUR-CL (EPC): A61K009/48; A61K047/18

ABSTRACT:

CHG DATE=20030403 STATUS=O>Pharmaceutical compositions for the effective oral delivery of a parathyroid hormone, PTH, as well as methods for administration of the compositions are provided. Additionally, methods for stimulating new bone formation and treating and/or preventing osteoporosis are also provided.

WEST

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L4: Entry 4 of 4

File: DWPI

Feb 27, 2003

DERWENT-ACC-NO: 2003-278518

DERWENT-WEEK: 200327

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TITLE: Oral compositions comprising parathyroid hormone fragments and N-(5-chlorosalicyloyl)-8-aminocaprylic acid, for treating e.g. osteoporosis

INVENTOR: AZRIA, M; BATEMAN, S D

PATENT-ASSIGNEE:

ASSIGNEE CODE
NOVARTIS AG NOVS
NOVARTIS PHARMA GMBH NOVS

PRIORITY-DATA: 2001US-313048P (August 17, 2001)

PATENT-FAMILY:

PUB-NO WO 2003015822 A1 PUB-DATE

February 27, 2003

LANGUAGE

PAGES M

015

MAIN-IPC A61K047/18

DESIGNATED-STATES: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LT LU LV MA MD MK MN MX NO NZ OM PH PL PT RO RU SE SG SI SK TJ TM TN TR TT UA US UZ VC VN YU ZA ZW AT BE BG CH CY CZ DE DK EA EE ES FI FR GB GR IE IT LU MC NL PT SE SK TR

APPLICATION-DATA:

PUB-NO

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APPLNO

DESCRIPTOR

WO2003015822A1

August 16, 2002

_2002WO\EP09181

INT-CL (IPC): A61 K 38/29; A61 K 47/18; A61 P 19/08; A61 P 19/10

ABSTRACTED-PUB-NO: WO2003015822A

BASIC-ABSTRACT:

NOVELTY - A composition (C1) for oral delivery of parathyroid hormone comprising a parathyroid hormone fragment selected from PTH (1-28) to PTH (1-41), and N-(5-chlorosalicyloyl)-8 aminocaprylic acid $(\underline{5-CNAC})$, is new.

DETAILED DESCRIPTION - An INDEPENDENT CLAIM is also included for use of C1 for stimulating new bone formation and treating or preventing osteoporosis. The PTH is also recombinant PTH or recombinant hPTH.

ACTIVITY - Osteopathic.

Capsules were prepared comprising: (A) 800 micro g hPTH, or (B) 800 micro g hPTH and 400 mg $\frac{5-\text{CNAC}}{2}$ disodium salt, and administered orally to rhesus monkeys. Blood samples were collected at intervals up to 6 hours after administration. Plasma hPTH levels were determined by radioimmunoassay.

The hPTH plasma concentration following administration of capsule (A) was zero at all time points, compared with results for (B) at 0.25, 0.75, 1, 1.5, 3, 4 and 6 hours after dosing of 105, 482, 809, 206, 17, 0 and 0 pg/ml respectively.

MECHANISM OF ACTION - None given in the source material.

USE - For stimulating new bone formation, and treating or preventing osteoporosis (claimed), in humans and animals.

CHOSEN-DRAWING: Dwg.0/0

TITLE-TERMS: ORAL COMPOSITION COMPRISE PARATHYROID HORMONE FRAGMENT N ACID TREAT

OSTEOPOROSIS

DERWENT-CLASS: B05

CPI-CODES: B04-J04B; B04-J04B0E; B10-D03; B14-N01;

CHEMICAL-CODES:

Chemical Indexing M1 *01* Fragmentation Code M423 M431 M782 M905 P624 P625 P714 Q233 Specfic Compounds AA17MK AA17MT AA17MM

Chemical Indexing M1 *02* Fragmentation Code M417 M423 M431 M782 M905 P624 P625 P714 Q233 Specfic Compounds A00H1K A00H1T A00H1M

Chemical Indexing M1 *03* Fragmentation Code M423 M431 M782 M905 P624 P625 P714 Q233 Specfic Compounds AA17LK AA17LT AA17LM

Chemical Indexing M1 *04*

Fragmentation Code

D011 D601 F011 F012 F014 F019 F423 F521 F599 G010 H211 H4 G100 H1 H101 H183 H2 H405 H484 H5 H598 H599 H8 н9 Ј0 J014 J1 J173 J3 L250 L299 M210 M211 M271 M282 M311 J373 K0 L2M312 M313 M314 M315 M323 M331 M332 M333 M340 M342 M343 M349 M371 M381 M393 M423 M431 M511 M523 M531 M540 M782 M904 M905 P624 P625 P714 Q233 Specfic Compounds A05BLK A05BLT A05BLM

Chemical Indexing M2 *05*

Fragmentation Code

G015 G100 H4 H401 H441 H6 H602 H641 H8 J331 M280 M315 M321 M332 M342 J012 J1 J171 J3 M381 M391 M414 M431 M510 M520 M531 M540 M782 M904 M905 P624 P625 P714 Q233 Specfic Compounds ASLM9K ASLM9T ASLM9M

Chemical Indexing M6 *06*

Fragmentation Code

M905 P624 P625 P714 Q233 R111 R280 R501 R520 R521

SECONDARY-ACC-NO: